

PATENT
Attorney Docket Number 46620.830001.US3
Express Mail Label No. EV269463051US

IN RE UNITED STATES PATENT APPLICATION

FOR

CERVICAL PLATE

OF

JEFFREY J. THRAMANN, M.D.

AND

MICHAEL FULTON, M.D.

CERVICAL PLATE

RELATED APPLICATIONS

This application is a continuation-in-part of United States Patent Application Serial No. 10/178,371, filed June 24, 2002, titled CERVICAL PLATE, now United States Patent Number 6,062,257. This application also is related to United States Patent Application Serial No. 10/178,656, filed June 24, 2002, titled IMPACTOR FOR USE WITH CERVICAL PLATE.

FIELD OF THE INVENTION

The present invention relates to apparatuses and methods for treating and correcting spinal abnormalities and, more particularly, to cervical plates and artificial discs useful in procedures relating to correction of abnormalities in the spine

BACKGROUND OF THE INVENTION

The vertebrae of the human spine are arranged in a column with one vertebra on top of the next. Between each vertebra exists an intervertebral disc that transmits force between adjacent vertebrae and provides a cushion between the adjacent vertebrae.

Sometimes, back pain is caused by degeneration or other deformity of the intervertebral disc ("diseased disc"). Conventionally, surgeons treat diseased discs by surgically removing the diseased disc and inserting a bone graft in the space vacated by the diseased disc. The adjacent vertebrae are then immobilized relative to one another. Eventually, the vertebrae grow into one solid piece of bone.

Currently, it is difficult to insert the bone graft into the vacated space and fuse the adjacent vertebrae. The current process of inserting a bone graft and

PATENT
Attorney Docket Number 46620.830001.US3
Express Mail Label No. EV269463051US

fusing the adjacent vertebrae will be explained with referring to FIGS. 1 and 2.

FIG. 1 shows two adjacent vertebrae 102 and 104. Located between vertebrae 102 and 104 is an intervertebral space 106 partially filled by a bone graft 108.

When the bone graft 108 is first inserted into the intervertebral space 106, the

30 adjacent vertebrae 102 and 104 are manually kept apart by the surgeon using, for example, a retracting device (not shown). As shown in FIG. 2, once the bone graft 108 is placed, the surgeon releases the adjacent vertebrae 102 and 104 allowing them to squeeze the bone graft 108 and hold the bone graft 108 in place.

35 To immobilize the vertebrae 102 and 104 with the bone graft 108 in place, the surgeon next applies a cervical plate 202 over the adjacent vertebrae 102 and 104. Cervical plate 202 may have a central viewing window 204 and one or more screw holes 206, in this example four screw holes 206a-206d are shown. Four bone screws (which will be identified by reference numerals 208a-208d) 40 would be screwed into the vertebrae using the screw holes 206 to anchor the cervical plate to the vertebrae and immobilize the vertebrae with respect to one another.

As can be appreciated, attaching the cervical plate 202 using the bone screws 208 is a difficult endeavor. Generally, a temporary screw (not shown) is 45 placed in one of the screw holes, for example 206a. Bone screw 208c would then be partially screwed into the bone at screw hole 206c. The temporary screw in hole 206a would be replaced by bone screw 208a, which would be tightened. Then the other bone screws 208 would be screwed into the bone in a cross point manner. The ability of the cervical plate to move freely in relation to the 50 vertebrae 102 and 104 and the bone graft 108 until the bone screws anchor the plate causes difficult in attaching the cervical plate. This is made more difficult because, generally, only a portion of the cervical plate is visible to the surgeon at any given moment (due to space constraints and surgical tools).

PATENT
Attorney Docket Number 46620.830001.US3
Express Mail Label No. EV269463051US

While the above example relates to replacement of one intervertebral disc
55 between two adjacent vertebrae, sometime it is necessary to replace two or more discs spanning three or more vertebrae. The problems associated with replacing one disc become more exacerbated the more discs and vertebrae that our involved.

Due to the small margins for error in placing the bone screws into the
60 vertebrae, it would be desirous to develop a cervical plate that was not as free to move prior to attachment with the bone screws.

SUMMARY OF THE INVENTION

To attain the advantages and in accordance with the purpose of the invention, as embodied and broadly described herein, apparatuses to facilitate the insertion of a bone graft into an intervertebral space and positioning of a cervical plate are provided. In particular, a cervical plate having an attachment mechanism that attaches the bone graft to the cervical plate prior to the cervical plate being inserted into the intervertebral space. The vertebra would hold the graft and the cervical plate in position to facilitate the anchoring of the cervical
65 plate to vertebrae.
70

The present invention further provides screw back out prevention mechanisms to prevent the bone screws anchoring the cervical plate from backing out.

The foregoing and other features, utilities and advantages of the invention
75 will be apparent from the following more particular description of a preferred embodiment of the invention as illustrated in the accompanying drawings. Further, the advantages and purpose of the invention will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.

PATENT
Attorney Docket Number 46620.830001.US3
Express Mail Label No. EV269463051US

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the present invention, and together with the description, serve to explain the principles thereof. Like items in the drawings are referred to using the same numerical reference.

85 FIG. 1 shows adjacent vertebrae with a bone graft;
FIG. 2 shows adjacent vertebrae with a bone graft and cervical plate;
FIG. 3 shows adjacent vertebrae with a bone graft and cervical plate having an attachment mechanism illustrative of the present invention;
FIG. 4 shows a cross-section of the bone graft and cervical plate of FIG.
90 3;
FIG. 5 shows an alternative attachment mechanism illustrative of the present invention;
FIG. 6 is a flowchart 600 illustrating use of the present invention;
FIG. 7; shows an impactor illustrative of the present invention;
95 FIG. 8 shows the impactor of FIG. 7 with a cervical plate illustrative of the present invention;
FIG. 9 is a flowchart illustrative of a use of the impactor consistent with the present invention;
FIGS 10A and 10B show an embodiment of a screw back out prevention
100 device consistent with the present invention;
FIG. 11 shows another embodiment of a screw back out prevention device consistent with the present invention;
FIG. 12 shows another embodiment of a screw back out prevention device consistent with the present invention;
105 FIG. 13 shows still another embodiment of a screw back out prevention device consistent with the present invention; and
FIG. 14 shows still another embodiment of a screw back out prevention device consistent with the present invention.

DETAILED DESCRIPTION

110 Some embodiments of the present invention are described with reference to FIGS. 3 to 14. In particular, FIGS. 3 and 4 show a cervical plate 300 and bone graft 302. Cervical plate 300 has a viewing window 304, screw holes 306, and an attachment mechanism 400 (shown in phantom in FIG. 3). As best seen in FIG. 4, cervical plate 300 has attachment mechanism 400 attaching the bone graft 302 to the cervical plate 300. While cervical plate 300 could be made of numerous biocompatible materials, it is believed cervical plate 300 should be made of bio absorbable material. Bio absorbable or resorbable devices are generally known in the art, see for example, United States Patent 6,241,771, titled RESORBABLE INTERBODY SPINAL FUSION DEVICES, issued to Gresser et al.,
115 on June 5, 2001, incorporated herein by reference.

120

Attachment mechanism 400 can be any of a number of different attachment mechanisms. For example, as shown in FIG. 4, attachment mechanism 400 comprises a pin or stud attached to the cervical plate inserted into a hole or detent in the bone graft 302. Alternatively, attachment mechanism 400 could be a spike inserted into bone graft 302 without bone graft 302 having a corresponding hole or detent to receive the spike, similar to a thumb tack. Alternatively, attachment mechanism 400 could comprise a pin or stud attached to the bone graft 302 inserted into a hole or detent in cervical plate 300. Also, attachment mechanism 400 could be any style snap lock or friction fitting, such as the cavity formed in FIG. 5 between protrusions 504, explained in more detail below. It would be possible to provide barbs and/or lips on attachment mechanism 400 to facilitate the connection. Moreover, while two attachment mechanisms 400 are shown, more or less attachment mechanisms could be used. Further, attachment mechanism 400 could be an adhesive layer between the cervical plate 300 and bone graft 302. Still further, attachment mechanism 400 could be a screw device so that bone graft 302 and cervical plate 300 are

125

130

135

PATENT
Attorney Docket Number 46620.830001.US3
Express Mail Label No. EV269463051US

attached using a screw mechanism. Finally, the cervical plates 300 could be made as a single integral unit with the bone graft 302, although that would be difficult due to the numerous sizes and shapes of bone grafts and plates
140 necessary to perform the surgery.

FIG. 5 shows cervical plate 500 attached to a bone graft 502 by prongs 504 on bone graft 502. As shown, prongs 504 attached to the bone graft grasp cervical plate 500 forming a frictional engagement. Alternatively, but not shown, cervical plate 500 could have prongs that grasp bone graft 502.

145 As one of ordinary skill in the art would recognize on reading this disclosure, the number of ways the bone grafts could be attached to the cervical plate is numerous. To the extent alternative attachment means are not expressly identified above, this description should not be limited to the embodiments identified and described above. Rather, the specific embodiments identified are
150 for illustrative purposes.

FIG. 6 is a flowchart 600 illustrating a method of using the present invention. In particular, the surgeon fits a bone graft into the intervertebral space, step 602. Then, with the bone graft in place and the adjacent discs holding the bone graft in place, the surgeon sizes a cervical plate, step 604. Once the cervical plate and bone graft are sized, the surgeon removes the plate and graft from the patient, and attaches the bone graft to the cervical plate, step 606.
155 Next, the combination bone graft and plate device is placed in the intervertebral space such that the adjacent discs hold the bone graft and plate in place, step 608. The cervical plate is then anchored to the adjacent vertebral bodies, step 610. Because surgeon attached the cervical plate to the bone graft, and the adjacent vertebrae hold the bone graft in place, the cervical plate remains fixed in place while the surgeon anchors the plate to the vertebrae.
160

As one of ordinary skill in the art would recognize on reading the above disclosure, the same general device and procedure is used when inserting

165 multiple bone grafts. For example, if fusing four vertebrae, a surgeon would
need to place three bone grafts. Conventionally, the three bone grafts are sized
and placed in the intervertebral space and a cervical plate is sized for the three
grafts. Using the present invention, the three bone grafts could all be removed
and attached to the cervical plate and then refitted into the patient. However, it
170 is believed attaching multiple bone grafts to the cervical plate would make it
difficult to fit the device into the patient. It is believed to be more efficient to
insert bone grafts and size the bone grafts and cervical plate, then remove one of
the bone grafts while leaving other bone grafts in the spine. The removed bone
graft would be attached to the plate. The one bone graft with the cervical plate
175 attached is refitted into the patient and screws can be used to anchor the entire
device with the one bone graft providing the stability for the cervical plate.

As mentioned above, inserting the bone graft and cervical plate includes
using a retracting device to hold the adjacent discs apart, inserting the bone
grafts and sizing the cervical plate, removing cervical plate and the retracting
180 device, allowing the adjacent discs to squeeze the bone graft, then replacing and
anchoring the cervical plate. A difficulty arises using the present invention
because the retracting devices need to be removed prior to placing and anchoring
the cervical plate. Thus, when the bone graft is removed and attached to the
cervical plate, the retracting devices need to be removed prior to replacing the
185 combined bone graft and cervical plate. However, on removing the retracting
devices, the adjacent discs move together making it difficult to insert the bone
graft between the adjacent discs.

FIG. 7 shows an impactor 700 capable of opening the space between the
discs to ease the insertion of the bone graft attached to the cervical plate.
190 Impactor 700 has a handle 702, a cervical plate holder 704, and prongs 706
forming cavity 708. Impactor 702 could have various numbers of prongs, but it
is believed two prongs work well. Cervical plate holder 704 is designed to hold

the cervical plate such that the prongs 706 extend downward beyond the cervical plate and bone graft attachment. Prongs 706 could be spaced to form cavity 708 such that placing the cervical plate in the cavity 708 would form a friction fitting releasably coupling the cervical plate to the impactor 700. The prongs 706 would act as a wedge to separate the adjacent discs allowing placement of the bone graft in the intervertebral space. Once the bone graft is placed, the impactor 700 would be completely removed from the patient. Thus, the cervical plate and impactor would be releasably coupled prior to insertion. FIG. 8 shows a top side elevation view of the impactor 700 holding a cervical plate 802. Cervical plate 802 is shown without a viewing window, but one could be used if desired.

FIG. 9 is a flowchart 900 illustrating using the impactor 700 with the cervical plate 802. For convenience, flowchart 900 is described for insertion of a single bone graft. One of skill in the art will recognize on reading the disclosure, however, that the device and procedure would be usable with insertion of multiple bone grafts. Initially, the surgeon fits a bone graft into the intervertebral space, step 902. Then, with the bone graft in place and the adjacent discs holing the bone graft in place, the surgeon sizes a cervical plate, step 904. Once the cervical plate and bone graft are sized, the surgeon removes the plate and graft from the patient, and attaches the bone graft and the cervical plate, step 906. Next, the impactor is releasably attached to the cervical plate, step 908. The impactor with the cervical plate and bone graft is used to separate the adjacent vertebrae, step 910. With the impactor holding the adjacent vertebrae apart, the bone graft is inserted in the intervertebral space such that the cervical plate is placed to be anchored to the adjacent vertebrae, step 912. The impactor is removed allowing the adjacent vertebrae to hold the bone graft and cervical plate in place, step 914. Finally, the cervical plate is anchored to the vertebrae, step 916.

Once surgically placed and anchored, cervical plate bone screws have a tendency to become loose, which is commonly referred to as backing out. Many devices have been devised to inhibit bone screws from backing out; however, none are particularly satisfactory.

225 Referring now to FIGS. 10A and 10B, a cervical plate 1000 with a back out prevention device 1002 in accordance with one embodiment of the present invention is shown. While the respective vertebrae have not been specifically shown in FIGS. 10A and 10B, cervical plate 1000 has been surgically implanted, and bone screws 1004 have been threaded into vertebral bodies through screw holes 1006 in plate 1000. A surface 1008 of plate 1000 contains at least one channel 1010 or groove. Back out prevention device 1002 comprises a cover 1012 and locking extension 1014 (best seen in FIG. 10B). Cover 1012 is sufficiently large to allow at least one perimeter edge 1016 of cover 1012 to extend over a head 1018 of screw 1004. When installed, edge 1016 is substantially aligned with head 1018 and prevents backing out of screw 1004.

230 Locking extension 1014 comprises one or more elastic prongs 1020, for example biocompatible plastic or spring metal. Prongs 1020 fit into channel 1010 to hold back out prevention device 1002 in place. To facilitate placement of prongs 1020 into channel 1010, cover 1012 may have at least one access port 1022 through which a tool (not specifically shown) can be inserted. The tool would flex prong 1020 such that prong 1020 easily fits into channel 1010. When the tool is removed, prong 1020 would tend to return to its original position and apply a frictional force to seat back out prevention device.

235

240

As shown by FIG. 10B, one embodiment of back out prevention device 1002 comprises cover 1012 with multiple prongs 1020 forming an inverted V shape. Prongs 1020 have a distal end 1024 with a locking edge 1026. In this case, locking edge 1026 comprises a shoulder or protrusion. As shown in FIG. 10B, locking edge 1026 could have a wedge shape to facilitate insertion of

prongs 1020 into channel 1010. In this case, use of the tool and access port 1022
250 may be unnecessary. Correspondingly, channel 1010 includes an engaging edge
1028. In this case, engaging edge 1028 comprises a lip or undercut. Of course,
locking edge 1026 could comprise a hollow and engaging edge 1028 could
comprise a corresponding protrusion, etc. Similarly, surface 1008 could have a
raised extension with protrusions and cover 1012 could have a channel with a lip
255 or shoulder. The channel of cover 1012 would be aligned with raised extensions
on surface 1008 forming a fitting, such as a snap lock or a frictional engagement.

While shown as a square or rectangular shape, cover 1012 can be formed
of many shapes and/or configurations. For example, cover 1012 could be
elliptical, circular, some other polygon, linear, an arc or curve, convex or
260 concave, irregular, a zig-zag, a letter shape, or the like. Further, as shown head
1018 resides above plate 1000 and cover plate 1012 resides above head 1018;
however, one of skill in the art would recognize on reading the disclosure, that
head 1018 and cover plate 1012 could be countersunk such that the head 1018
and cover plate 1012 reside substantially in the same plane as plate 1000.

265 Referring now to FIG. 11, another cervical plate 1100 with two back out
prevention devices 1102d and 1102u is shown. Prevention device 1102d is
shown deployed and prevention device 1102u is shown undeployed. Plate 1100
would be surgically implanted and bone screws 1104 threaded into the vertebral
body through screw holes 1106.

270 Prevention devices 1102 comprise a plurality of bars 1108 having a
deployed state (shown by prevention device 1102d) and an undeployed state
(shown by prevention device 1102u). In the deployed state, prevention device
1102d has a peripheral edge 1110 on bars 1108 that extend over a head 1112 of
screws 1104. In the undeployed state, prevention device 1102u has bars 1108
275 relatively closer to each other where peripheral edge 1110 does not extend over
head 1112, which makes screws 1104 freely movable. When deployed, a locking

device 1114, such as a pin, stud, screw, clip, cam, or the like is inserted or rotated between bars 1108 to lock prevention device 1102d in the deployed state. For example, after bars 1108 are deployed, a screw could be inserted to maintain
280 the separation. Alternatively, a cam could be rotated to maintain separation. Locking device 1114 would be removed to undeploy the prevention device. While prevention device 1102 is shown sized similar to a single screw head, prevention device 1102 could have bars 1108 that extend the length of the cervical plate so only one prevention device is necessary for multiple sets of
285 screws.

FIG. 12 shows a top plan view of another back out prevention device 1200 consistent with the present invention. Unlike prevention devices 1000 and 1100, which generally prevent screws from backing out by engaging a screw head, prevention device 1200 engages, for example, a thread of a screw or a notch located, for example, in the screw head. Back out prevention device 1200 includes a bushing 1202 and at least one locking pin 1204, in which three pins 1204 are shown in this case. Bushing 1202 forms a ring or thread through which a screw (not specifically shown) can be threaded. A spring 1206 or other elastic device pushes locking pin 1204 radially inward such that pins 1204 provide sufficient force on at least one thread or notch of the bone screws (not specifically shown in FIG. 12). Spring 1206 should not be construed as a conventional helical spring, but could be a number of elastic devices including, for example, elastic plastics, air loaded dampers, magnetics, shaped memory alloys, or the like. Thus, spring or spring loaded should be used generically to mean a device with elastic movement ability. Basically, spring 1206 needs to provide sufficient outward force to seat pin 1204 against a thread, notch, or surface of the screw or screw head, but be sufficiently resilient to allow the screw to be threaded into bone. (Notice, spring 1206 and pin 1204 could be combined into a single unit using). Spring 1206 could be flush between the pin
290
295
300

PATENT
Attorney Docket Number 46620.830001.US3
Express Mail Label No. EV269463051US

305 1204 and bushing or, as shown, spring 1206 could reside in a channel 1208 in
bushing 1202.

FIGS. 13 and 14 show cross-sectional views of screw back out prevention device 1300 and 1400, respectively. FIG. 13 shows a portion of a cervical plate 1302 about a screw hole 1304. Residing in screw hole 1304 would be a bushing 310 1306 that contains a notch 1308, groove, or channel. A screw would be threaded into vertebral bodies (not specifically shown in FIG. 13) through screw hole 1304 such that screw head 1310 resides as shown. Screw head 1310 has a notch 1312, groove, or channel, corresponding to notch 1308. Residing in notch 1308 and notch 1312 is a self-bonding material 1314, such as high molecular weight 315 polyethylene, nylons, and biopolymers and other self-bonding material commonly used in the aeronautical and automotive industries. Instead of self-bonding material 1314, material 1314 could be replaced with heat fusible material, pressure sensitive material, radiation curing, or other adhesives that require activation to adhere. Self-bonding material 1314 provides back out 320 prevention because when the screw is threaded into the vertebral bodies bonding material 1314 in notch 1308 engages bonding material 1314 in notch 1312 and bonds. Thus, screw head 1310 is held in place. Although shown in a notch, material 1314 could be layered, such as by a coating or spray, on bushing 1306 and screw head 1310.

325 Similarly, FIG. 14 shows a portion of a cervical plate 1402 about a screw hole 1404. Residing in screw hole 1404 is a screw head 1406. Screw hole 1404 has sidewalls 1408. Residing on sidewalls 1408 exists at least one strip of self-bonding material 1410. In this case, for example, self-bonding material 1410 is a spray on type of material. Screw head 1406 has exterior sidewalls 1412. 330 Residing on sidewalls 1412 exists at least one strip of self-bonding material 1410 corresponding to the strip of self-bonding material 1410 on sidewalls 1408.

PATENT
Attorney Docket Number 46620.830001.US3
Express Mail Label No. EV269463051US

Again, instead of a spray or coating, material 1410 could reside in a notch on sidewall 1408 and sidewall 1412.

Alternatively to a self-bonding material, other materials may be used. For
335 example material 1410 (or 1314) may be a type of heat fusion plastic. To use
heat fusion, once the screw is threaded and the materials align, a heat activation
signal would be applied to fuse the materials. Other bonding materials, such as
epoxies, acrylics (such cyanoacrylates and anaerobics), silicones, pastes, tapes,
and glues, and the like could be used for bonding material 1410 (or 1314), but
340 would inhibit threading of the screw as well as be useful as a screw back out
prevention device.

While the invention has been particularly shown and described with
reference to some embodiment thereof, it will be understood by those skilled in
the art that various other changes in the form and details may be made without
345 departing from the spirit and scope of the invention.